US ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND (USAMRDC)
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP)
FISCAL YEAR 2021 (FY21) AUTISM RESEARCH PROGRAM (ARP)

DESCRIPTION OF REVIEW PROCEDURES

The programmatic strategy implemented by the FY21 ARP called for applications in response to program announcements (PAs) for four award mechanisms released in March 2021:

- Clinical Trial Award (CTA)
- Clinical Translational Research Award (CTRA)
- Idea Development Award (IDA)
- Career Development Award (CDA)

Pre-applications were received for these four PAs in May 2021 and were screened in June 2021 to determine which investigators would be invited to submit a full application. Pre-applications were screened based on the evaluation criteria specified in the PAs.

Applications were received for these four PAs in August 2021 and were peer reviewed in September 2021. Programmatic review was conducted in December 2021.

In response to the IDA PA, 108 pre-applications were received, and the Principal Investigators (PIs) of 41 of these were invited to submit a full application. Thirty three compliant applications were received, and three (9%) were recommended for funding, for a total of $1.98 million (M).

In response to the CDA PA, 37 pre-applications were received, and the PIs of 20 of these were invited to submit a full application. Eighteen compliant applications were received, and four (22%) were recommended for funding, for a total of $2.70M.

In response to the CTRA PA, 26 pre-applications were received, and the PIs of 13 of these were invited to submit a full application. Twelve compliant applications were received, and one (8%) was recommended for funding, for a total of $0.92M.

In response to the CTA PA, 25 pre-applications were received, and the PIs of 14 of these were invited to submit a full application. Thirteen compliant applications were received, and three (23%) were recommended for funding, for a total of $7.76M.

Submission and award data for the FY21 ARP are summarized in the table below.

Table 1. Submission/Award Data for the FY21 ARP*

Mechanism	Pre-Applications Received	Pre-Applications Invited (%)	Compliant Applications Received	Applications Recommended for Funding (%)	Total Funds
IDA	108	41 (38%)	33 (30.5%)	3 (9%)	$1.98M
CDA	37	20 (54%)	18 (48%)	4 (22%)	$2.70M
CTRA	26	13 (50%)	12 (46.2%)	1 (8%)	$0.92M
CTA	25	14 (56%)	13 (52%)	3 (23%)	$7.76M
Total	**163**	**88 (45%)**	**76 (46.6%)**	**11 (14%)**	**$13.36M**

*These data reflect funding recommendations only. Partnering PI counts are not included in this data. Pending FY21 award negotiations, final numbers will be available after September 30, 2022.

THE TWO-TIER REVIEW SYSTEM

The USAMRDC developed a review model based on recommendations of the 1993 Institute of Medicine (IOM) (now called the National Academy of Medicine) of the National Academy of Sciences report, *Strategies for Managing the Breast Cancer Research Program: A Report to the Army Medical Research and Development Command*. The IOM report recommended a two-tier review process and concluded that the best course would be to establish a peer review system that reflects not only the traditional strengths of existing peer review systems, but also is tailored to accommodate program goals. The Command has adhered to this proven approach for evaluating competitive applications. An application must be favorably reviewed by both levels of the two-tier review system to be funded.

THE FIRST TIER—Scientific Peer Review

The CTA, CTRA, IDA, and CDA applications were peer reviewed in September 2021 by six panel(s) of researchers, clinicians, and consumer advocates that included 60 scientists and 10 consumer reviewers. Each peer review panel included a Chair, an average of 10 scientific reviewers, an average of 2 consumer reviewers, and a nonvoting Scientific Review Officer. The primary responsibility of the panelists was to review the technical merit of each application based upon the evaluation criteria specified in the relevant PA.

Individual Peer Review Panels

The Chair for each panel presided over the deliberations, and the applications were individually discussed. The Chair called on the assigned reviewers for an assessment of the merits of each application using the evaluation criteria published in the appropriate PA. Following a panel discussion, the Chair summarized the strengths and weaknesses of each application, and the panel members then rated the applications confidentially.

Application Scoring

Evaluation Criteria Scores: Panel members were asked to rate each peer review evaluation criterion as published in the appropriate PA. A scale of 1 to 10 was used, with 1 representing the lowest merit and 10 the highest merit, using whole numbers only. The main reasons for obtaining the criteria ratings were to (1) place emphasis on the published evaluation criteria and

provide guidance to reviewers in determining an appropriate overall score and (2) provide the applicant, the Programmatic Panel, and the Command with an informed measure of the quality regarding the strengths and weaknesses of each application. The evaluation criteria scores were not averaged or mathematically manipulated in any manner to connect them to the global or percentile scores.

Overall Score: To obtain an overall score, a range of 1.0 to 5.0 was used (1.0 representing the highest merit and 5.0 the lowest merit). Reviewer scoring was permitted in 0.1 increments. Panel member scores were averaged and rounded to arrive at a two-digit number (1.2, 1.9, 2.7, etc.). The following adjectival equivalents were used to guide reviewers: Outstanding (1.0–1.5), Excellent (1.6–2.0), Good (2.1–2.5), Fair (2.6–3.5), and Deficient (3.6–5.0).

Summary Statements: The Scientific Review Officer on each panel was responsible for preparing a Summary Statement reporting the results of the peer review for each application. The Summary Statements included the evaluation criteria and overall scores, the peer reviewers' written comments, and the essence of the panel discussions. This document was used to report the peer review results to the Programmatic Panel. It is the policy of the USAMRDC to make Summary Statements available to each applicant when the review process has been completed.

THE SECOND TIER—Programmatic Review

Programmatic review was conducted in December 2021 by the FY21 Programmatic Panel, which is comprised of a diverse group of basic and clinical scientists and consumer advocates, each contributing special expertise or interest in autism. Programmatic review is a comparison-based process that considers scientific evaluations across all disciplines and specialty areas. Programmatic Panel members do not automatically recommend funding applications that were highly rated in the technical merit review process; rather, they carefully scrutinize applications to allocate the limited funds available to support each of the award mechanisms as wisely as possible. The programmatic review criteria published in the PAs were as follows: ratings and evaluations of the scientific peer review panels; programmatic relevance; relative impact; program portfolio balance; military relevance, and adherence to the intent of the award mechanism. After programmatic review, the Commanding General, USAMRDC, approved funding for the applications recommended during programmatic review.